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EXAMINER
LU, FRANK WEI MIN

ART UNIT	PAPER NUMBER
1634	15

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/779,376	FAN ET AL.	
	Examiner	Art Unit	
	Frank W Lu	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5,9-16,19-23,26 and 30-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5,9,10,12-16,19-23,26 and 30-34* is/are rejected.

7)☒ Claim(s) *11 and 12* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☒ The proposed drawing correction filed on *14 November 2002* is: a)☒ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

1. Applicant's response to the office action filed on November 13, 2002 has been entered as Paper No:14. The claims pending in this application are claims 5, 9-16, 19-23, and 30-34. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn.

Drawings

2. The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on November 14, 2002 have been approved. A proper drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The correction to the drawings will not be held in abeyance.

Claim Objections

3. Claim 9 is objected to because of the following informalities: "eluting said probe off said solid support" should be "eluting said probe from said solid support".

4. Claim 26 is objected to because of the following informalities: "a first target-specific sequence a first base at an interrogation position" should be "a first target-specific sequence comprising a first base at an interrogation position".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 22 is rejected as vague and indefinite over "wherein said target sequence is attached to said support by a method selected from the group consisting of labeling said target sequence with a functional attachment moiety that binds said support" because "labeling said target sequence with a functional attachment moiety that binds said support" is a process for labeling and is not an attachment method. Does this phrase mean attaching said target sequence with a functional attachment moiety that is capable of binding to said support to said support by interacting said functional attachment moiety with said support. Please clarify.

8. Claim 22 is rejected as vague and indefinite in view of the phrase "absorption of said target sequence on a charged support" because it is unclear whether "a charged support" and "said support" in the claim represents the same thing or not. Please clarify.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -

> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

10. Claims 5, 13, and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Barany *et al.,* (US Patent No. 6,027,889, filed on May 28, 1997).

Barany *et al.,* teach detection of nucleic acid sequence differences using coupled ligase detection and polymerase chain reactions. As shown in Figures 12-17, a first oligonucleotide probe having a target-specific portion and a 5' upstream primer-specific portion, and a second oligonucleotide probe having a target-specific portion and a 3' downstream primer-specific portion were hybridized adjacent to one another on a corresponding target nucleotide sequence and were ligated together in a ligase chain reaction. However, if there was a mismatch in ligation end of the first or second probe, this mismatch would interfere with such ligation. Then unligated the first probe and the second probe were removed with Exo I and PCR-amplified using an upstream primer containing the same sequence as the 5' upstream primer-specific portion of the ligation product sequence (in the first probe) and a downstream primer complementary to the 3' downstream primer-specific portion of the ligation product sequence (in the second probe) wherein one primer had a detectable reporter label. Finally, PCR products were hybridized with a DNA array with different capture oligonucleotides immobilized at different particular sites and had nucleotide sequences complementary to the unique nucleotide sequences across the ligation

junctions of given probe sets, and the labels of the PCR products captured on the DNA array at particular sites were detected as recited in steps f) and g) of claims 5 and 32 (see Figures 12-17 and columns 9, 10, 25-28, and 79-90). Note that: (1) the first probe and second probe was considered as first and second ligation probe as recited in claims 5 and 32; (2) since the claims did not require that the adaptor sequence was different from UUP or DUP, 5' upstream primer-specific portion in the first probe and 3' downstream primer-specific portion in the second probe were considered as UUP and DUP or an adaptor sequence as recited in claims 5 and 32 wherein the adaptor sequence was considered to be identical to UUP or DUP; (3) since claims 5 and 32 do not require that step c) must perform before step d), Exo I digestion step was considered as step c) recited in claims 5 and 32; (4) as shown in Figure 12, base G in left probe (a first ligation probe) that hybridized to mutant sequence was considered as a first base at an interrogation position as recited in claim 5 or an interrogation position that was complementary to said detection position in a first ligation probe as recited in claim 32; and (5) claim 13 was considered as basic PCR steps including repeated denaturation, annealing and extension.

Therefore, Barany *et al.,* teach all limitations recited in claims 5, 13, and 32.

Response to Arguments

In page 9, sixth paragraph bridging to page 11, fourth paragraph of applicant's remarks, applicant argued that "Barany does not teach an adapter sequence in the ligation primer," since "[C]laims 5 and 13 clearly state that the adapter sequence is an independent elements of the present invention." and "Barany outlines the use of a 'zipcode' component, similar to the 'adapter' in a subsequent step.".

This argument has been fully considered but it is not persuasive toward the withdrawal of the rejection because Barany *et al.,* did teach an adapter sequence in the ligation primer. Since the claims did not require that the adaptor sequence was different from UUP or DUP, the adaptor sequence was considered to be identical to UUP or DUP in the rejection.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 14-16 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barany *et al.,* (1997) as applied to claims 5, 13, and 32 above, and further in view of Walt *et al.,* (US Patent No. 6,327,410 B1, filed on September 11, 1998).

The teachings of Barany *et al.,* have been summarized previously, *supra.*

Barany *et al.,* did not disclose an array recited in claims 14-16 and 34.

Walt *et al.*, do teach an array comprising a substrate such as a fiber optical bundle recited in claims 16 and 34 with a patterned surface with discrete sites such as wells recited in claim 15 and a population of microspheres comprising at least a first subpopulation and a second subpopulation wherein said first subpopulation comprises a first nucleic acid and second subpopulation comprises a second nucleic acid, and wherein said microspheres are randomly distributed on said surface such that said discrete sites contain microspheres recited in claim 14 (see Figures 7A and 7B, columns 3, 4, and 28-30).

Therefore, in the absence of an unexpected result, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have performed the method recited in claims 5 and 32 using an array recited in claims 14-16 and 34 in view of the patents of Barany *et al.,* and Walt *et al.*. One having ordinary skill in the art would have been motivated to modify the method of Barany *et al.,* because the simple replacement of one kind of nucleic acid array (a regular oligonucleotide array) from another kind of nucleic acid array (an array with microspheres having immobilized nucleic acids) during the process of determining the identification of a nucleotide at a detection position in a target sequence would have been, in the absence of an unexpected result, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made because the replacement of one kind of nucleic acid array from another kind of nucleic acid array during the process of determining the identification of a nucleotide at a detection position in a target sequence would not change the method steps of the experiment.

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

Also note that there is no invention involved in combining old elements is such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

Response to Arguments

In page 11, last paragraph bridging to page 13, third paragraph of applicant's remarks, applicant argued that: (1) "the Examiner has used the claimed invention as a template to piece together the teachings of Walt and Barany." and 'the Examiner has impermissibly used hindsight reconstruction to create the claimed invention" since " the present invention lays out a blueprint for a possible combination of the two teachings. Before this invention, Barany did not contain any impetus to use the bead based platforms of Walt."; and (2) neither of patents from Barany *et al.*, and Walt *et al.*, "contains the element of a ligation probe comprising an adapter sequence.".

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection. First, in response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge

gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Second, Barany *et al.,* did teach an adapter sequence in the ligation primer. Since the claims did not require that the adaptor sequence was different from UUP or DUP, the adaptor sequence was considered to be identical to UUP or DUP in the rejection.

13. Claims 10, 13, 19-22, 26, 31, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang *et al.,* (US Patent No. 5,876,924, filed on July 31, 1996) in view of Barany *et al.,* (1997).

Regarding claims 10, 13, 19-22, 26, 31, and 33, Zhang *et al.,* teach nucleic acid amplification method hybridization signal amplification method. As shown in Figures 1 and 2, the two oligonucleotide probes (Capture/Amp-probe-1 and Amp-probe-2) were first hybridized adjacent to one another on a corresponding target nucleotide sequence of the target nucleic acid in a sample wherein the Capture/Amp-probe-1 was 3'-biotinylated. Then the complex comprising target nucleic acid-probes was separated from any unbound reactants using streptavidin-coated paramagnetic beads as recited in claims 10, 19, 20, and 31 and the probes were ligated together in a ligation chain reaction. Ligated product of Capture/Amp-probe-1 and Amp-probe-2 were used as a template for PCR (see Figures 1 and 2, and columns 10-17). This method could be used to detect a single mutation in a target (see column 6, first paragraph). Note that: (1) since claims 26 and 33 did not require that step a) must perform before step b), binding of target nucleic acid-probe complex to streptavidin-coated paramagnetic beads was considered to provide a support on

which the target sequence was immobilized recited in step a) of claims 26 and 33; (2) since the claims did not require that the adaptor sequence was different from UUP or DUP, (d) domain of Capture/Amp-probe-1 and (g) domain of AMP-PROBE-2 were considered as DUP and UUP or adaptor sequences respectively wherein the adaptor sequence was considered to be identical to UUP or DUP; (3) streptavidin-coated paramagnetic beads were considered as a double-stranded moiety as recited in claim 10 since they bound to and separated the complex comprising target nucleic acid-probes which was double stranded from any unbound reactants; (4) the target nucleic acid was considered to be indirectly immobilized on streptavidin-coated paramagnetic beads as recited in claims 19 and 21; (5) biotinylated Capture/Amp-probe-1 was considered as a functional attachment moiety recited in claim 22 since this probe attached the target nucleic acid to streptavidin-coated paramagnetic beads in the target nucleic acid-probe complex; and (6) a base located in 5' of capture/AMP-probe was considered as an interrogation position as recited in claims 26 and 33 (see Figure 1).

Zhang *et al.,* did not disclose steps g) and h) of claims 26 and 33.

The teachings of Barany *et al.,* have been summarized previously, *supra.* Barany *et al.,* also teach steps g) and h) of claims 26 and 33 (see above).

Therefore, in the absence of an unexpected result, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have performed the method recited in claims 26 and 33 using a PCR product made by Zhang *et al.,* as a hybridization probe in view of the patents of Barany *et al.,* and Zhang *et al.*. One having ordinary skill in the art would have been motivated to modify the method of Barany *et al.,* because the

simple replacement of one well known LDR/PCR method (LDR/PCR method of Barany *et al.,*) from another well known LDR/PCR method (LDR/PCR method of Zhang *et al.,*) in order to make a hybridization probe would have been, in the absence of an unexpected result, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made since using different methods to make a hybridization probe would not change the experimental results.

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

Also note that there is no invention involved in combining old elements is such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

Response to Arguments

In page 13, fourth paragraph bridging to page 15, last paragraph of applicant's remarks, applicant argued that: (1) "none of the reference contains any motivation to combine these references";" (2) the skilled artisan would not have been motivated to modify either of the references because both references teach the same assay"; and (3)"[N]one of these references contains the element of the ligation probe comprising an adapter sequence.".

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection. First, in response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by

combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Zhang *et al.,* teach all limitations in claims 26 and 33 except steps g) and h) while Barany *et al.,* disclose steps g) and h) of claims 26 and 33. Since the knowledge of LDR/PCR method was generally available to one of ordinary skill in the art at time the invention was made. It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have performed the method recited in claims 26 and 33 using a PCR product made by Zhang *et al.,* as a hybridization probe in view of the patents of Barany *et al.,* and Zhang *et al.,* because the simple replacement of one well known LDR/PCR method (LDR/PCR of Barany *et al.,*) from another well known LDR/PCR method (LDR/PCR of Zhang *et al.,*) in order to make a hybridization probe would change the experimental results. Second, Zhang *et al.,* did teach the ligation probe comprising an adapter sequence. Since the claims did not require that the adaptor sequence was different from UUP or DUP, (d) domain of Capture/Amp-probe-1 and (g) domain of AMP-PROBE-2 were considered as DUP and UUP or adaptor sequences respectively wherein the adaptor sequence was considered to be identical to UUP or DUP in the rejection.

14. Claims 9, 23, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang *et al.,* (1996) in view of Barany *et al.,* (1997) as applied to claims 13, 19-22, 26, 31, and 33 above, and further in view of Seradyn Particle Technology (November 1996).

The teachings of Zhang *et al.,* and Barany *et al.,* have been summarized previously, *supra.*

Seradyn Particle Technology (page 7) confirms streptavidin-coated paramagnetic beads taught by Zhang *et al.,* comprising a plastic material as recited in claims 23 and 30 since these beads had polystyrene core.

Zhang *et al.,* Barany *et al.,* and Seradyn Particle Technology do not disclose claim 9 wherein the target sequence is labeled with a binding ligand. However, Zhang *et al.,* teach steps b) to d) in claim 9 except the probe is labeled with a binding ligand in step a) (see column 8 and 10-13).

Therefore, in the absence of an unexpected result, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have removed non-hybridized probes using a method recited in claim 9 in view of the prior art of Barany *et al.,* Zhang *et al.,* and Seradyn Particle Technology. One having ordinary skill in the art would have been motivated to modify the method of Zhang *et al.,* because a method for labeling different nucleic acids with a binding ligand was known in the art at the time the invention was made and the simple replacement of one well known nucleic acid separation method (based on the interaction between a ligand on a target nucleic acid with its binding partner) from another well known nucleic acid separation method (based on the interaction between a ligand on a nucleic

acid probe with its binding partner) during the process of determining the identification of a nucleotide at a detection position in a target sequence would have been, in the absence of an unexpected result, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made since using different methods to remove non-hybridized probes would not change the experimental results.

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

Also note that there is no invention involved in combining old elements is such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Claim 11 and12 are objected to as being dependent upon a rejected base claim, but appears to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

17. No claim is allowed.

18. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the patent Analyst of the Art Unit, Ms.Chantae Dessau, whose telephone number is (703) 605-1237.

Frank Lu
January 21, 2003

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